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Annals of Oncology 29 (Supplement 9): ix46–ix66, 2018
doi:10.1093/annonc/mdy432

GASTROINTESTINAL TUMOURS, NON-COLORECTAL

1490 Efficacy and safety of ramucirumab (RAM) in Asian and non-Asian patients with advanced hepatocellular carcinoma (HCC) and elevated alpha-fetoprotein (AFP): Subgroup analysis from two randomized studies

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Background: The etiological factors and management of HCC vary by geographical region[1]. REACH-2[2] and REACH[3] showed significant survival benefits of RAM treatment for HCC in patients (pts) with baseline AFP ≥400 ng/mL. We conducted a pooled subgroup analysis to investigate the efficacy and safety of RAM in Asian and non-Asian pts from REACH-2 and REACH (high AFP subpopulation).

Methods: Pts were randomized to receive RAM 8 mg/kg IV or placebo (PL) once every two weeks, plus best supportive care, until disease progression or unacceptable toxicity. Endpoints included overall survival (OS), progression-free survival (PFS), objective response rate (ORR), disease control rate (DCR), and safety. Kaplan-Meier analysis and Cox proportional hazards regression were performed for OS and PFS. Efficacy analyses were stratified by study.

Results: Across the two studies, 291 Asian pts were randomized to RAM (168) or PL (123); 251 non-Asian pts were randomized to RAM (148) or PL (103). Baseline characteristics were generally balanced between treatment arms in Asian and non-Asian patients. RAM significantly improved median OS in Asian pts; 8.08 months (m) RAM vs 4.76 m PL (stratified hazard ratio [HR] 0.73, 95% confidence interval [CI]: 0.56, 0.95), and non-Asian pts; 7.98 m RAM vs 5.22 m PL (HR 0.65, 95% CI: 0.49, 0.86). RAM significantly improved median PFS in Asian pts; 2.73 m RAM vs 1.45 m PL (HR 0.58, 95% CI: 0.44, 0.76), and non-Asian pts; 3.06 m RAM vs 1.87 m PL (HR 0.55, 95% CI: 0.41, 0.73). ORR was 4.2% RAM vs 0.8% PL (Asian pts) and 6.8% RAM vs 1.0% PL (non-Asian pts); DCR was 53.6% RAM vs 33.3% PL (Asian pts) and 59.5% RAM vs 41.7% PL (non-Asian pts). The most common grade ≥3 adverse event occurring in the RAM arm of Asian and non-Asian pts was hypertension (7.7% and 16.9%, respectively).

Conclusions: This subgroup analysis demonstrates survival benefits of RAM treatment in Asian and non-Asian patients with advanced HCC and AFP ≥400 ng/mL. Treatment was well tolerated, with similar safety profiles between Asian and non-Asian pts.
References: [1]Fong et al. Cancer 2014;120:2824-38. [2]Zhu et al. J Clin Oncol 2018;36:suppl. abstr 4003. [3]Zhu et al. Lancet Oncol 2015;16:859-70.

Editorial acknowledgement: Medical writing assistance was provided by Lisa Cossens and editorial assistance by Antonia Baldo from Syneos Health.

Clinical trial identification: NCT01140347, NCT02435433.

Legal entity responsible for the study: Eli Lilly and Company.

Funding: Eli Lilly and Company.

Disclosure: Y-K. Kang: Consultant: Eli Lilly and Company, BMS, Ono, Bayer, Blueprint, M. Kudo: Member on an advisory board, board of directors: Eli Lilly Japan KK., H-Y. Lim: Member of the steering committee: Bayer; Advisory board meetings: Bayer, Ipsen, Eisai & Ono., C-H. Hsu: Membership on an advisory board: BMS, Ono, MSD, Merck/Sorono, Novartis Roche; Recipient of research funding: MSD., A. Vogel: Honoraria: Eli Lilly and Company, Bayer, MSD, Roche, Novartis, AstraZeneca, Beigene. R. Cheng, I. Carton: Full time employee, stock holder: Eli Lilly and Company. P. Abada: Full time employee: Eli Lilly and Company. Y. Hsu: Full time employee, stock owner, patent pending: Eli Lilly and Company. A. Zhu: Advisory and consulting roles: BMS, Eisai, Bayer, Merck, Eli Lilly and Company. All other authors have declared no conflicts of interest.